

171. The spinal fusion implant of claim 169 further comprising a plurality of surface roughenings for engaging said adjacent vertebral bodies and for maintaining said implant in place, said surface roughenings being present on at least a portion of said outer surface of said implant.

172. The spinal fusion implant of claim 169 in which said body includes a longitudinal central axis and at least one truncated side forming a planar surface parallel to said central axis.--

REMARKS

Applicant brings to the Examiner's attention that four (4) signed Form PTO 1449's submitted with the Information Disclosure Statements dated July 9, 1997; December 19, 1997; January 14, 1999; and March 10, 1999, have yet to be received by the applicant. It is respectfully requested that the Examiner provide copies of all four (4) signed Form 1449's to the applicant. Further, applicant filed a Supplemental Information Disclosure Statement on November 3, 1999, after the mailing date of the Office Action, but within three months of the references submitted therein being cited in a foreign search report in a corresponding application. Applicant requests that the Examiner acknowledge his consideration of the references submitted in the Supplemental Information Disclosure Statement by signing the Form PTO 1449 and return it to applicant.

In the Office Action, the Examiner rejected claims 1-4, 5-7, 9, 10, 17-22, 26-32, 34, 35, 42-48, 53-57, 59, 60, 67-72, 77-82, 89-94, 98-105, 107, 108, 115-120, 124-126, 131, and 132 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,458,638 ('638) to Kuslich in view of Kuslich '638. Claims 8, 13, 33, 38, 58, 63, 80, 85, 106, 111, 128, and 134 were rejected by the Examiner under 35 U.S.C. § 103(a) as being unpatentable over Kuslich '638 in view of Kuslich '638 along with U.S. Patent No. 4,904,260 ('260) to Ray. Claims 11, 14-16, 23, 24, 36, 39-41, 49, 50, 61, 64-66, 73, 74, 83, 84, 86-88, 95, 96, 109, 112-114, 121, 122, 127, 129, 133, and 135 were rejected by the Examiner under 35 U.S.C. § 103(a) as being unpatentable over

Kuslich '638 in view of Kuslich '638 and further in view of U.S. Patent No. 4,878,915 to Brantigan.

Independent claims 1 and 124, as now amended recite an implant with bone engaging means having an outer locus that is frusto-conical "along at least a portion of the length of said implant nearer said trailing end than said insertion end." Independent claims 26, 53, 98, and dependent claim 2 which depends from claim 1, as now amended, are directed to an implant having a body that is frusto-conical "along a sufficient portion of said body that is adapted to contact the adjacent vertebral bodies when implanted in the spine so as to maintain an angulation of the adjacent vertebral bodies relative to one another." Independent claims 137 and 145, as now amended are directed to an implant having either a body or bone engaging means having arcuate portions with "a distance between said arcuate portions increasing from said first end to said second end along a sufficient portion of the length of said implant so as to maintain angulation of the vertebral bodies."

Contrary to the Examiner's assertion, Kuslich '638 at Fig. 2A does not teach a "frusto-conical spinal implant" as claimed by applicant. Kuslich '638 also does not teach a spinal implant with bone engaging means having an outer locus that is frusto-conical along at least a portion of the length of the implant nearer the trailing end than the insertion end. Instead, Kuslich discloses a threaded cylindrical implant wherein:

"threading 26, 28 (see Fig. 2) adjacent leading end 14 is tapered as shown by angle  $A_1$  (which is preferably about  $15^\circ$ , see FIG. 2). Away from the tapered end 14, and adjacent the trailing end 16, the threads 26, 28 present flat, annular surfaces 30 which are in alignment and parallel to shell 22.

Accordingly, the thread profile presents a generally bullet-shaped profile which is cylindrical along the majority of the body 12 and tapers inwardly

toward axis X-X at the leading end 14.” (Kuslich ‘638, Col. 4, lines 21-29)

(Emphasis added).

As shown in Fig. 2A of Kuslich ‘638, “leading end 14’ includes a sharp point 15’ to better assist the insertion and advancement of the body 12’ into the intervertebral space.” (Kuslich ‘638, Col. 7, lines 37-40). The Kuslich ‘638 implant does not have a substantially frusto-conical configuration along a sufficient portion of the implant that is adapted to contact the adjacent vertebral bodies when implanted so as to maintain an angulation of the adjacent vertebral bodies relative to one another.

Independent claim 77, as now amended, is directed to a spinal fusion implant having a body with a substantially cylindrical configuration and an outer surface including a plurality of posts having a head and a stem wherein the head is wider than the stem and the posts are spaced apart along at least a portion of the outer surface for engaging the implant to the adjacent vertebral bodies. Kuslich ‘638 discloses a cylindrical implant with threads on its external surface and an oval implant with arcuate ribs 128 on its exterior. (Kuslich ‘638, Col. 4, lines 13-20; and Col. 8, lines 39-52). Kuslich ‘638 does not disclose a spinal fusion implant with posts as claimed by applicant.

Brantigan ‘915 discloses a plug 11 having a knurled roughened peripheral surface 11b forming pyramid-like pits 11c for facilitating bone ingrowth; a device 31 with a pitted periphery 31b forming a myriad of small pores to facilitate bone ingrowth; a device 32 with longitudinally spaced circular ribs 32b that form dish-like prongs or barbs tilted toward the threaded end of the plug so that they will deflect to slide into the prepared sites; an implant 33 having an external periphery that is externally threaded 33b; and an implant 34 with a polymeric resin cover 34c having upright projecting bristles 34d. (Brantigan ‘915, Col. 6, lines 7-64). Brantigan ‘915 does not disclose a spinal fusion implant with posts as recited in applicant’s claimed invention.

Independent claim 131, as now amended, is directed to a spinal fusion implant being formed of a mesh-like material “capable of supporting two adjacent vertebral bodies in a spaced apart relationship to each other.” No such structure is taught, disclosed or suggested by Kuslich ‘638 or Ray ‘260. Kuslich ‘638 discloses a threaded cylindrical implant with a hollow cylindrical shell 22 that surrounds and defines an interior chamber 24. Threads 26 and 28 are formed on the exterior of the shell and a plurality of openings 32 formed radially through the shell 22 and threads 26, 28. (Kuslich ‘638, Col. 4, lines 7-67). No mesh-like material is disclosed.

Ray ‘260 discloses a prosthetic intervertebral disc capsule having a diameter approximating the height of a human disc with an “outer layer 12 consisting of a network of strong, inert polymeric fibers interwoven with bioresorbable fibers which attract tissue ingrowth.” (Ray ‘260, Col. 4, lines 3-7; Col. 8, lines 35-37.) Ray ‘260 does not disclose a spinal fusion implant. Ray ‘260 also does not teach, disclose, or suggest a spinal fusion implant being formed of a mesh-like material capable of supporting two adjacent vertebral bodies in a spaced apart relationship to each other as claimed by applicant.

Applicant submits that Kuslich ‘638, Ray ‘260, or Brantigan ‘915, alone or in proper combination, do not anticipate, teach, or suggest, applicant’s claimed invention in independent claims 1, 26, 53, 77, 98, 124, 131, 137, and 145 or claims dependent therefrom. Accordingly, the rejection of claims 1-4, 5-7, 9, 10, 17-22, 26-32, 34, 35, 42-48, 53-57, 59, 60, 67-72, 77-82, 89-94, 98-105, 107, 108, 115-120, 124-126, 131, and 132 under 35 U.S.C. § 103(a) over Kuslich ‘638 in view of Kuslich ‘638; the rejection of claims 8, 13, 33, 38, 58, 63, 80, 85, 106, 111, 128, and 134 under 35 U.S.C. § 103(a) as being unpatentable over Kuslich ‘638 in view of Kuslich ‘638 along with Ray ‘260; and the rejection of claims 11, 14-16, 23, 24, 36, 39-41, 49, 50, 61, 64-66, 73, 74, 83, 84, 86-88, 95, 96, 109, 112-114, 121, 122, 127, 129, 133, and 135 under 35

U.S.C. § 103(a) as being unpatentable over Kuslich '638 in view of Kuslich '638 and further in view of Brantigan '915 have been overcome.

If there are any fees due in connection with the filing of this response, please charge our Deposit Account Number 50-1066. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for in the papers accompanying this response, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,  
MARTIN & FERRARO, LLP

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